IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket: 00415-03

Applicant: Herr, et al.

Invention: Recombinant Antibody Directed Against Human Sperm Antigen

Serial No: 10/031,783

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Art Unit: 1641

Examiner: James L. Grun

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Date: December 9, 2004 Sue Ann Carr

Declaration of Thomas R. Moench Under 37 CFR § 1.132

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

I, Thomas R. Moench, declare:

1. I am President of ReProtect, Inc., 703 Stags Head Road, Baltimore, Maryland 21286.

2. I do not hold any commercial interest in the subject matter of the above-identified patent application by Dr. John Herr et al., nor does ReProtect, Inc.

3. My *curriculum vitae* is submitted herewith. I received my M.D. degree from the Johns Hopkins University in 1976. I served as an Intern and then Assistant Resident

in Medicine at Johns Hopkins from 1976-1978 and then as a Senior Resident in Medicine at the University of Washington from 1978-1979. I returned to Johns Hopkins in 1979, and until 1994 served in various capacities of increasing importance and responsibility-from Postdoctoral Fellow, to Assistant Chief of Service, to Assistant Professor of Medicine, Division of Infectious Diseases. In 1994, I joined ReProtect, LLC as Medical Director. In 2003, I became President of ReProtect, Inc.

4. I have over twenty years of research experience in various aspects of cellular, molecular, and clinical aspects of inflammatory and infectious diseases, including contraception. In addition to my research publications, I am an inventor of several patents related to fertility and sterility. I have a broad background in the use of many immunological techniques, including the use of various kinds of antibodies and antibody fragments (see for example on my *curriculum vitae*:

Van Wielink, G., McArthur, J.C., Moench, T.R., Farzadegan, H., McArthur, J.H., Johnson, R.T. and Saah, A.: Intrathecal synthesis of anti-HIV IgG: Correlation with increasing duration of HIV-1 infection. Neurology 40: 816-819, 1990.

Zeitlin L, Whaley KJ, Sanna PP, Moench TR, Bastidas R, De Logu A, Williamson RA, Burton DR, Cone RA Topically applied human recombinant monoclonal IgG1 antibody and its Fab and F(ab')2 fragments protect mice from vaginal transmission of HSV-2. Virology; 225:213-5, 1996.

Zeitlin L, Whaley KJ, Sanna PP, Moench TR, Bastidas R, De Logu A, Williamson RA, Burton DR, Cone RA: Topically applied human recombinant monoclonal IgG1 antibody and its Fab and F(ab')2 fragments protect mice from vaginal transmission of HSV-2. Virology 225:213-5, 1996.

Castle PE, Whaley KJ, Hoen TE, Moench TR, Cone RA. Contraceptive effect of sperm-agglutinating monoclonal antibodies in rabbits. Biol Reprod 56:153-9, 1997.

Zeitlin L, Castle PE, Whaley KJ, Moench TR Cone RA: Comparison of an anti-HSV-2 monoclonal IgG and its IgA switch variant for topical immunoprotection of the mouse vagina. J Reprod Immunol 40:93-101, 1998.

Zeitlin L, Olmsted SS, Moench TR, Co MS, Martinell BJ, Paradkar VM, Russell DR, Queen C, Cone RA, and Whaley KJ: A humanized monoclonal antibody produced

in transgenic plants for immunoprotection of the vagina against genital herpes. Nature Biotechnology 16:1-5, 1998.

Zeitlin L, Cone RA, Moench TR, Whaley KJ. Preventing infectious disease with passive immunization. Microbes Infect 2000; 2:701-8.

Castle PE, Karp DA, Zeitlin L, Garcia-Moreno E B, Moench TR, Whaley KJ, Cone RA. Human monoclonal antibody stability and activity at vaginal pH. J Reprod Immunol. 2002; 56:61-76.).

5. I understand the Office Action issued June 10, 2004 in the above-identified application, as well as the art cited by the Examiner in said Office action.

6. With regard to the Examiner's assertion at page 2 of the Office Action that there is insufficient written description and guidance regarding claims 5, 6, 13, 14, and 41, I believe that one of skill in the art would "know for what condition a conjugate of a sperm-specific antibody with toxins, microbicides, or virucides would predictably function, other than delivery of a spermicidal toxin, in the absence of further description and guidance from applicant". Dependent claims 6 and 14 also specifically recite that the toxin is adenylate cyclase toxin. I believe that ample written description and guidance are provided in the specification as filed ant that one of ordinary skill in the art would understand what conditions are being targeted when toxins, microbicides, or virucides are conjugated to a sperm-specific antibody. It is known in the art that antibodies, as well as a wide variety other agents with varied modes of action, can be delivered for many uses, including contraception, disease treatment and disease prevention. For example, we showed that antibodies, as well at Fab and F(ab')2 fragments, can be applied topically as protection against HSV-2 infection (Zeitlin et al., 1996, Virology, 225:213-215); that antibodies can provide protection against genital herpes (Zeitlin et al., 1998, Nature Biotechnology, 16:1-5); and that BufferGel can be used for contraception and prevention of sexually transmitted diseases (Zeitlin et al., 2001, Sex. Tansm. Dis. 28:417-423). We also showed that membrane-modifying agents can be administered to block vaginal transmission of cell-associated HIV-1 (Khann et al., 2002, J. Clin. Invest., 109:205-211) and that bacterial vaginosis can be treated with a buffering vaginal microbicide (Mayer et

al., Clin Infect Dis 2001, 32:476-82; van de Wijgert et al., J AIDS 2001, ;26:21-27). Thus, it is evident that various types of agents useful for contraception, disease prevention, and disease treatment have been used and are known to those of ordinary skill in the art.

Based on these and other studies, and based on my knowledge of the use of antibodies and other agents as contraceptives or as regulators of pathogens and disease, I believe that one of ordinary skill in the art would understand how and when a recombinant antibody, coupled to an effector molecule such as a toxin, a virucide, or a microbicide, or a composition thereof, as recited in claims 5, 6, 13, 14, and 41 can be used to treat or prevent diseases, and how it could be used as a contraceptive.

7. Regarding the Examiner's rejection of claims 1-3, 7, 9-12, 33-36, 39, 40, and 42 as obvious over Herr et al. (U.S. Patent No. 5,830,472) in view of Owens et al. (J. Immunol. Methods, 1994, 168:149-165), and Bird et al. (Science, 1988, 242:423-426), it is my opinion that the aforementioned claims would not be obvious over the combination of references cited by the Examiner. None of the three references suggests to me, or motivates me, to combine or modify the references in an effort to arrive at the present invention. For the following reasons, it is my opinion that the Examiner has presented no evidence that there was any motivation or suggestion in Herr et al., Owens et al., or Bird et al. to combine or modify these references.

Regarding Herr et al., it does not teach the specific sequences of the present invention, nor does it teach the single chain antibody of the invention. As pointed out by the inventors in a prior response, the sequence of the light chain recited in Herr et al. was inaccurate. As discussed in the last response, a total of 31 nucleotides of the light chain sequence were incorrect as disclosed in the Herr et al., relative to the correct sequence reported in the present application. Therefore, the defective sequence published in the Herr patent would not allow the invention as claimed to be practiced. Furthermore, at column 9, lines 3-7, cited by the Examiner, Herr et al. merely states that the S19 monoclonal cDNA light and heavy chain sequences can be employed to provide recombinant antibodies. Thus, even if one of ordinary skill in the art would rely on a suggestion of Herr et al., they would not be able to practice the claimed invention

because they would not be using the correct sequence. Moreover, Herr et al. does not provide such an antibody and was merely reciting a list of possible uses. The statement by Herr et al., when analyzed in conjunction with the other references, would not have provided motivation to modify Herr or the other references, or to combine Herr with the other references cited by the Examiner. Furthermore, in the statement cited by the Examiner, Herr et al. was merely speculating about uses of antibodies or recombinant antibodies, while the present claims are composition claims, not method of use claims.

Furthermore, contrary to the assertion of the Examiner, the statement in Herr et al. at column 3, lines 12-24 is merely speculation about making recombinant antibodies. Herr et al. in fact provides no recombinant antibodies.

Owens et al., as a mini-review, merely encompasses genetic engineering of monoclonal antibodies. Owens et al. does not teach or suggest the use of a single chain antibody capable of binding to SAGA-1, consisting essentially of two specific sequences (i.e., SEQ ID NOs:1 and 3) which are bound to one another by a linker as recited in claim 1, nor does it suggest the other elements recited in the independent or dependent claims as asserted by the Examiner. Furthermore, contrary to the present invention, Owens et al. teaches that a single chain recombinant antibody would not be useful because a single chain antibody has the characteristic of monovalent binding. Owens et al. further cites two studies to support the proposition that multivalent antibodies should be used and that single chain monovalent antibodies should not be used (see Owens et al., page 156). Therefore, based on the teachings of Owens et al, one of ordinary skill in the art would not be motivated to prepare and use a single chain antibody, and in fact would be motivated to not to use a single chain recombinant antibody. In addition, because Owens teaches that a single chain monovalent antibody would not be effective, one of skill in the art would understand that even if a single chain antibody were prepared, there would not be a benefit such as decreased cost. In fact, based on the teachings of Owens, one of skill in the art would believe that there would be no benefits in preparing such a single chain recombinant antibody. Therefore, the findings of the present application are unexpected.

Bird et al. merely demonstrated that three monoclonal antibodies could be engineered to form single chains which still bind to their respective antigens. Bird et al. does not correct the deficiencies of Herr et al. and Owens et al. and does not teach or

suggest the use of a single chain antibody capable of binding to SAGA-1, consisting essentially of two specific sequences (i.e., SEQ ID NOs:1 and 3) which are bound to one another by a linker as recited in claim 1, nor does it suggest the other independent or dependent claims asserted by the Examiner. Owens et al. published six years after Bird et al. Owens et al. was a critical review of the state of antibody art at the time it was published. In fact, Owens et al. cites Bird et al., but merely cites Bird regarding linker use in constructing single chain molecules. Thus, even though Owens et al. was aware of Bird et al., Owens et al. still teaches that single chain antibodies not as useful because of reduced activity or potency, relative to multivalent antibodies (see page 156 of Owens). Therefore, one of ordinary skill in the art at the time the application was filed would have appreciated that, even with the earlier teachings of Bird et al., Owens teaches away from the use of single chain antibodies and any potential benefits which were merely posited by Herr et al. and Bird et al. The suggestions in these references regarding potential benefits referred to by the Examiner were merely invitations regarding further experimentation and no data or teachings were provided to support the suggestions.

Further evidence that the claimed invention is not obvious over the references cited by the Examiner is the fact that the three references were published in 1998 (Herr et al.), 1994 (Owens et al.), and 1988 (Bird et al.), and that the present application was not filed until 2000. Thus, from the time Bird et al. published in 1988 until the present application was filed twelve years later, no had conceived or reduced to practice the present invention as claimed. This supports my belief that it was not obvious to one of ordinary skill in the art at the time the present application was filed to combine the cited references and that there was no motivation or suggestion to do so.

It is my belief that the three references cited by the Examiner would not motivate or suggest to me or to one of ordinary skill in the art to combine the teachings of the references. Nor do I find anything in the references which would make it be obvious to combine the references. Furthermore, even if the references were combined, the resulting combination is not the claimed invention. Because the combination of the recited references does not result in the present invention, there would be no reasonable expectation of success in combining the cited references and arriving at the present invention. Therefore, for the reasons outlined above, I do not believe that the present

invention as claimed is obvious over Herr et al., Owens et al. and Bird et al.

8. I do not agree with the allegation by the Examiner that because Russell et al. (U.S. Patent No. 6,080,560) teaches single chain antibodies produced in plants, the combination of Herr et al., Owens et al., and Bird et al., in view of Russell et al., renders claim 38 obvious. Neither Herr et al., Owens et al., or Bird et al. teach or suggest a host cell comprising heterologous DNA encoding a single chain Fv fragment selected from the group consisting of SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:17 and SEQ ID NO:12, further wherein the host cell is a plant cell, as recited in claim 38 of the present application. Nor do any of the references provide a motivation to combine the references. For the reasons discussed above, I do not believe that Herr, Owens, and Bird provide any suggestion or motivation to combine those references. For example, Owens et al. teaches away from the present invention. Therefore, I do not believe that the combination of said references results in the invention as recited in claim 38.

Russell merely teaches that antibodies can be expressed in plant cells. Russell does not teach or suggest a host cell comprising heterologous DNA encoding a single chain Fv fragment selected from the group consisting of SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:17 and SEQ ID NO:12, further wherein the host cell is a plant cell, as recited in claim 38 of the present application. In addition, there is no motivation or suggestion in these references to use the teachings of Russell, nor is there a motivation or suggestion in Russell to adapt the teachings of Russell to the teachings of Herr, Owens, and Bird. Therefore, I believe that Russell et al. does not correct the deficiencies of Herr, Owens, and Bird and that this combination of references does not render claim 38 obvious. As a scientist, I can find nothing which connects the references in such a way as to make it obvious to combine them.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001

of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Thomas R. Moench

Thomas R. Moench, M.D.
President
ReProtect, Inc.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Thomas R. Moench, M.D.	President, ReProtect, Inc.

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Saint Olaf College	B.A.	1972	Chemistry
Johns Hopkins University	M.D.	1976	Medicine
Johns Hopkins University	Postdoctoral	1984	Infectious Diseases

PREVIOUS EMPLOYMENT:

1976-1978 Intern and Assistant Resident in Medicine, Johns Hopkins Hospital
1978-1979 Senior Resident in Medicine, University of Washington, Seattle, WA
1979-1980 Post-doctoral fellow, Division of Internal Medicine, Johns Hopkins Hospital
1980-1981 Assistant Chief of Service, Department of Medicine, Johns Hopkins Hospital
1981-1984 Post-doctoral fellow, Division of Infectious Diseases, Johns Hopkins Hospital
1984-1994 Assistant Professor, Department of Medicine, Division of Infectious Diseases, Johns Hopkins Hospital, Baltimore, MD
1994-2003 Medical Director, ReProtect, LLC, Baltimore, MD
2003-Present President, ReProtect, Inc., Baltimore, MD

PUBLICATIONS

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Zeitlin L, Olmsted SS, Moench TR, Co MS, Martinell BJ, Paradkar VM, Russell DR, Queen C, Cone RA, and Whaley KJ: A humanized monoclonal antibody produced in transgenic plants for immunoprotection of the vagina against genital herpes. Nature Biotechnology 16:1-5, 1998.

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